103D CONGRESS
1ST SESSION

S. 340

To amend the Federal Food, Drug, and Cosmetic Act to clarify the application of the Act with respect to alternate uses of new animal drugs and new drugs intended for human use, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 4 (legislative day, JANUARY 5), 1993

Mr. HEFLIN (for himself, Mr. PRESSLER, Mr. SHELBY, Mr. DASCHLE, Mr. CONRAD, Mr. CAMPBELL, Mr. BROWN, Mr. DECONCINI, Mrs. KASSEBAUM, Mr. DANFORTH, Mr. MACK, Mr. COATS, Mr. DORGAN, Mr. ROTH, Mr. HOLLINGS, Mr. WARNER, Mr. WOFFORD, Mr. FEINGOLD, Mr. INOUYE, Mr. CHAFEE, Mr. MCCONNELL, Mr. BOREN, Mr. PRYOR, Mr. KEMPTHORNE, Mr. CRAIG, Mr. EXON, Mr. REID, Mr. NICKLES, Mr. COCHRAN, Mr. JOHNSTON, Mr. BOND, Mr. GRASSLEY, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to clarify the application of the Act with respect to alternate uses of new animal drugs and new drugs intended for human use, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress finds that—

(1) the Federal Food, Drug, and Cosmetic Act currently permits the use of an animal drug, or a drug intended for human use, that is approved by the Food and Drug Administration, only in accordance with the specific labeling approved for the drug;

(2) there are not such approved animal drugs available to relieve pain and suffering, or to treat every specific disease or condition found, in each species of animal;

(3) it is sometimes necessary for veterinarians to use such an approved animal drug or approved drug intended for human use in a manner that is not in accordance with the label of the drug if—

(A) the health of an animal is immediately threatened; and

(B) suffering or death would result from failure to provide effective treatment; and

(4) veterinarians possess the professional training and medical judgment to administer drugs in a clinically-appropriate manner that benefits animals and safeguards the public health.

(b) PURPOSES.—The purposes of this Act are—

(1) to permit veterinarians to use such an approved animal drug, or approved drug intended for human use, for therapeutic purposes in animals in

a manner that is not specified on the label of the drug, if a valid veterinarian-client-patient relationship exists; and

(2) to permit the Secretary of Health and Human Services to establish conditions for such use as may be necessary to protect the public health.

SEC. 2. ALTERNATE USES.

Section 512(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)) is amended by adding at the end the following new paragraphs:

''(4) If an approval of an application filed under subsection (b) is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of section 501(a)(5), and shall be exempt from the regulations of section 502(f), with respect to a different use or intended use of the drug, if such use or intended use—

''(A) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship; and

''(B) is in compliance with regulations promulgated by the Secretary that establish such conditions for such use or intended use as may be necessary to protect the public health.

''(5) If an approval of an application filed under section 505 is in effect with respect to a particular use or intended use of a drug intended for human use, the drug shall not be deemed unsafe for the purposes of section 501(a)(5), and shall be exempt from the requirements of section 502(f), with respect to a use or intended use of the drug in non-food producing animals, if such use or intended use complies with the requirements specified in subparagraph (A) or (B) of paragraph (4).''.

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